

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A Corbin

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 11, 2003, from 8:30 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184, ext. 176, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

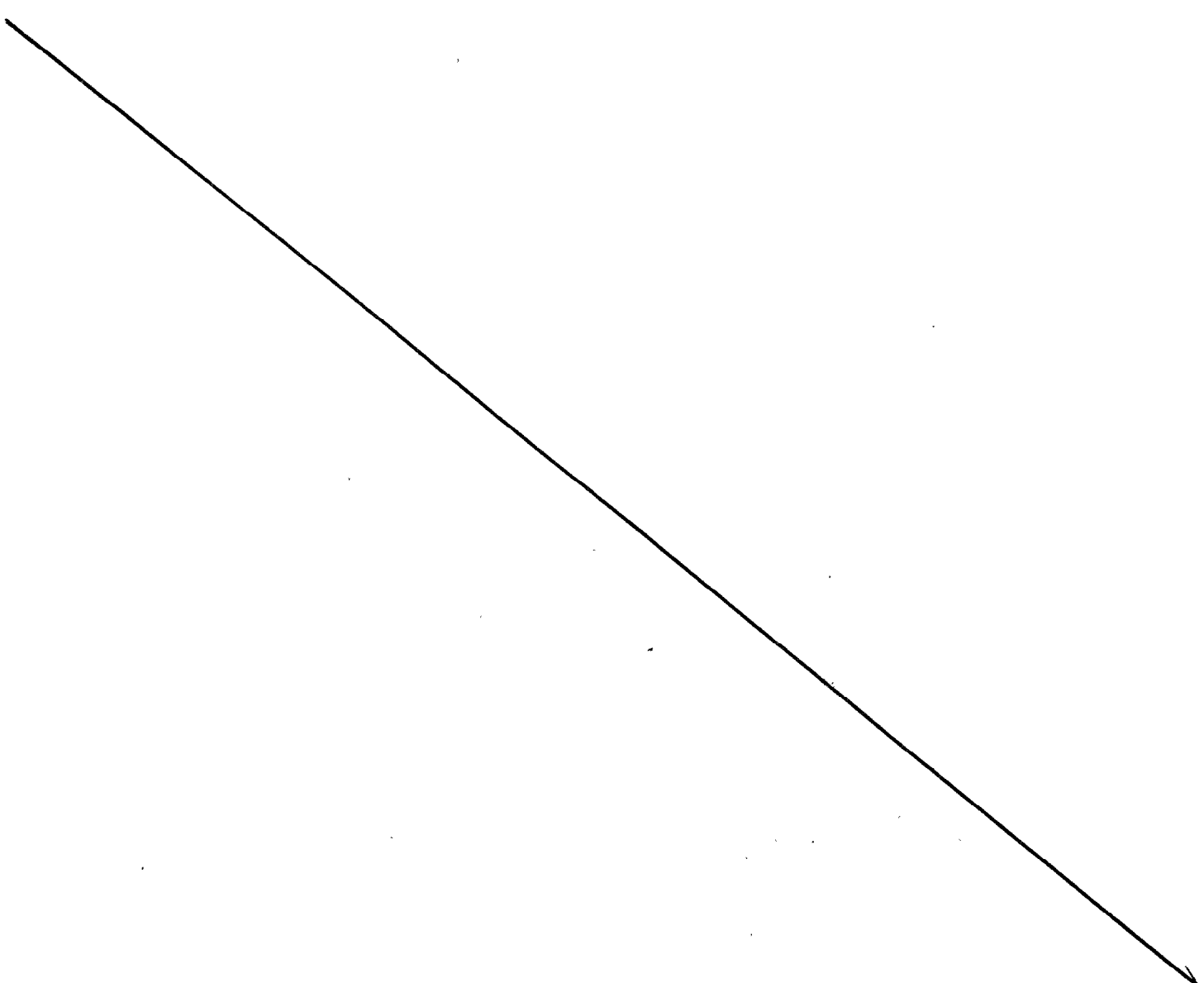
Agenda: The committee will discuss, make recommendations, and vote on the reclassification of the intervertebral body fusion device (cage) intended for spinal fusion procedures in skeletally mature adults with degenerative disc disease at one or two levels from C2–C7 and L2–S1 using autogenous bone graft. The device does not include combination products, such as the intervertebral body fusion device using morphogenic proteins and scaffolds. Background information for the topic, including the agenda and questions for the committee, will be available to the public no later than 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: On December 11, 2003, from 9 a.m. to 6 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 2003. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 11, 2003, from 8:30 a.m. to 9 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.


FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks, Conference Management Staff, at 301-594-1283, ext. 105, at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: November 14, 2003

November 14, 2003.



William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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